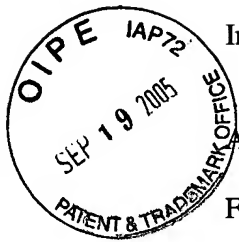


IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re Application of

Harald Berchtold

Examiner: Not Yet Assigned

Application No.: **10/696,011**

Art Unit: 1646

Filed: **October 29, 2003**

Title: **CRYSTALS OF INSULIN ANALOGS AND
PROCESSES FOR THEIR
PREPARATION**

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

September 15, 2005

Date of Deposit

Brian Pritchett
Signature

Brian Pritchett

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. 1.56, 1.97 AND 1.98

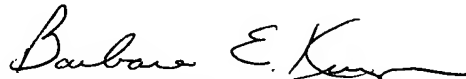
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Applicants submit herewith patents, publications, and other information of which they are aware, which they believe may be material, as defined in 37 C.F.R. 1.56(b), to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 C.F.R. 1.56(a). While the information referred to in this Information Disclosure Statement may be material pursuant to 37 C.F.R. 1.56(b), the filing of this Information Disclosure Statement is not intended to, pursuant to 37 C.F.R. 1.97(h), constitute an admission that any patent, publication or other information referred to is, or is considered to be, material to the patentability of this invention. Pursuant to 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information exists.

- ☒ (a) This Information Disclosure Statement is filed within the period set forth in §1.97(b) because it accompanies the new patent application submitted herewith, is filed within three months of the filing date of a national application or within three months of the date of entry of the national stage as set forth in §1.491 in an international application, or is believed to be filed before the mailing date of a first Office Action on the merits, or before the mailing of a first office action after the filing of a request for continued examination under §1.114 whichever event occurs last. However, in the event that the first office action has been mailed, the Commissioner is authorized to charge any fees under 37 C.F.R. 1.17(p) or credit any overpayment to Account No. **18-1982**.

- ☐ (b) This Information Disclosure Statement is filed after the period set forth in 37 C.F.R. 1.97(b), but is believed to be filed before the mailing date of a final action under §1.113 or a notice of allowance under §1.311, whichever occurs first.
- ☐ (1) The undersigned attorney certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement;
- ☐ (2) The undersigned attorney certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned attorney after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this statement; or
- ☐ (3) This Information Disclosure Statement is accompanied by a transmittal letter in which payment of the fee set forth in §1.17(p) and required by 37 C.F.R. 1.97(c) is authorized.

Respectfully submitted,



Barbara E. Kurys, Reg. No. 34,650
Attorney/Agent for Applicant

Aventis Pharmaceuticals Inc.
Patent Department
Route #202-206 / P.O. Box 6800
Bridgewater, NJ 08807-0800
Telephone (908) 231-2965
Telefax (908) 231-2626
Aventis Docket No. DEAV2002/0069 US NP

☒

+

A circular stamp from the Office of Intellectual Property (OIPE). The text "OIPE" is at the top, "PATENT & TRADEMARK OFFICE" is at the bottom, and "SEP 19 2005" is in the center. "IAP72" is also visible at the top right.

Complete if Known

(use as many sheets as necessary)

Sheet 1 of 3

Application Number	10/696,011
Filing Date	10-29-2003
First Named Inventor	BERCHTOLD, et. al.
Group Art Unit	1646
Examiner Name	Not Yet Assigned
Attorney Docket Number	DEAV2002/0069 - US - NP

[illegible][illegible]

Examiner
Signature

Date
Considered

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.

+

Please type a plus sign (+) inside this box → ☒

PTO/SB/08B (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.



Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/696,011
				Filing Date	10-29-2003
				First Named Inventor	BERCHTOLD, et. al.
				Group Art Unit	1646
				Examiner Name	Not Yet Assigned
Sheet	2	of	3	Attorney Docket Number	DEAV2002/0069 - US - NP

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials [*]	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		BAKER, E.N., et. al., The Structure Of 2Zn Pig Insulin Crystals At 1.5 A Resolution, Phil. Trans. R. Soc. Land, (1998), Vol. 319, pp. 369 - 456	
		BENTLEY, G.A., et. al., Role Of B13 Glu In Insulin Assembly; The Hexamer Structure Of Recombinant Mutant (B13 Glu Gln) Insulin, Journal Of Molecular Biology, (1992), Vol. 228, pp. 1163 - 1176	
		BERGER M., et. al., Towards More Physiological Insulin Therapy In the 1990s, Diabetes Research and Clinical Practice, (1989), Vol. 6, pp. S25 - S31	
		BERNSTEIN, F.C., et. al. , The Protein Data Bank: A Computer-Based Archival File For Macromolecular Structures, Journal Of Molecular Biology, (1977), Vol. 112, pp. 535 - 542	
		BOLLI, G.B., et. al., The Pharmacokinetic Basis Of Insulin Therapy In Diabetes Mellitus, Diabetes Research and Clinical Practice, (1989), Vol. 6, pp. S3 - S16	
		BRANGE, J., et. al., Neutral Insulin Solutions Physically Stabilized By Addition Of Zn2+, Diabetic Medicine, (1986), Vol. 3, pp. 532 - 536	
		DIXON, G.H., et. al., Regeneration Of Insulin Activity From The Separated And Inactive A and B Chains, Nature, (1960), Vol. 188, No. 4752, pp. 721 - 724	
		DRURY, P.L., et. al., Diabetic Nephropathy, British Medical Bulletin, (1989), Vol. 45, No. 1, pp. 127 - 147	
		HOME, P.D., et. al., Insulin Treatment: A Decade Of Change, British Medical Bulletin, (1989), Vol. 45, No. 1, pp. 92 - 110	
		KANG, S., et. al., Subcutaneous Insulin Absorption Explained By Insulin's Physicochemical Properties Evidence From Absorption Studies Of Soluble Human Insulin And Insulin Analogues In Humans, Diabetes Care, (1991), Vol. 14, No. 11, pp. 942 - 948	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → ☒

PTO/SB/08B (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/696,011
				Filing Date	10-29-2003
				First Named Inventor	BERCHTOLD, et. al.
				Group Art Unit	1646
				Examiner Name	Not Yet Assigned
Sheet	3	of	3	Attorney Docket Number	DEAV2002/0069 - US - NP

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		KEMMLER, W., et. al., Studies On The Conversion Of Proinsulin To Insulin, The Journal Of Biological Chemistry, (1971), Vol. 246, No. 22, pp. 6786 - 6791	
		KOHNER, E.M., et. al., Diabetic Retinopathy, British Medical Bulletin, (1989), Vol. 45, No. 1, pp. 148 - 173	
		MARSHALL, R.C., et. al., Protein Oligomer Composition, Preparation of Monomers and Constituent Chains, Practical Protein Chemistry - A Handbook (1986) S. 49-53	
		The Diabetes Control And Complications Trial Research Group, The Effect Of Intensive Treatment Of Diabetes On The Development And Progression Of Long-Term Complications In Insulin-Dependent Diabetes Mellitus, The New England Journal Of Medicine, (1993), Vol. 329, No. 14, pp. 977 - 986	
		WARD, J.D., et. al., Diabetic Neuropathy, British Medical Bulletin, (1989), Vol. 45, No. 1, pp. 111 - 126	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.